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| 10/537,493 | 06/03/2005 | Hiroshi Horiuchi | Q88366 | 4639 |

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| EXAMINER | |
|---|---|
| BADR, HAMID R | |

| ART UNIT | PAPER NUMBER |
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| 1794 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/537,493 | HORIUCHI ET AL. | |
| | Examiner | Art Unit | |
| | HAMID R. BADR | 1794 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *5,6,8-12,14 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6,8-12,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicants' amendment filed 11/30/2009 is acknowledged.

1. Claims 5-6, and 8-12, and 14-15 are being considered on the merits.

Note: The Declaration under 37 C.F.R. 1.132, by Mr. Hiroshi Horiuchi, has been reviewed and reconsidered.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 5-6 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castberg et al. (US 5,453,256; hereinafter R1) in view of Kamiya (EP 1 082 907; hereinafter R2).

3. R1 discloses a method of converting pasteurized milk into fermented milk in which the pasteurized milk is high temperature heat treated and carbonated with carbon dioxide and inoculated with starter culture followed by fermentation of the inoculated milk. (Abstract).

4. R1 discloses that while the conventional yoghurt process employs 43C as the incubation temperature; an incubation temperature of 30C may be employed (Col. 3, lines 14-17).

5. R1 discloses the advantage of the invention as shortening the fermentation time necessary and can thus lead to economics of the fermented milk and is particularly applicable to yoghurt production (Col. 4, lines 29-34). Therefore, the fermentation period is shorter than a fermentation period without using the inert gas as presently claimed.

**6. R1 discloses that the stimulation of lactic bacterial growth is, in part, due to removal of oxygen from the milk and thus lowering the redox potential. (col. 4, lines 40-43). R1 further adds that high oxygen content (e. g. in milk) retards the growth of yoghurt bacteria. (col. 4, lines 48-50)**

**7. R1 discloses that the high temperature heat treatment of milk can be at 80-85C for 20-30 minutes or at 90-95C for 3minutes. (col. 3, lines 10-15)**

**8. R1 discloses a method of converting milk into fermented milk comprising supplying heat treated milk, introducing the carbon dioxide into the heat treated milk and introducing the starter culture into the milk to instigate fermentation of milk. (col. 3, line 67 to col. 4 line 6, Examples 1 and 4).**

**9. Given the order of steps of sterilization, gasification, and fermentation of the yogurt substrate, as disclosed by R1, steps of claim 15 would be obvious to an artisan.**

10. R1 teaches using 1200 ppm of carbon dioxide which stimulates the starter culture and as a result the incubation time is reduced by 20% (Col. 5, lines 5-10). Given the effect of lowering the oxygen content of the medium (col. 4, lines 40-43) on the starter culture in reducing the incubation time, the finding, by the applicant, that the "increase of the lactic acid activity could be promoted without using any additives such as fermentation promoting substances by using inert gas to reduce the dissolved oxygen concentration" (Page 5 of the instant application, lines 10-21) was known in the art at the time the invention was made.

11. R1 gives an incubation temperature of 37C while using yoghurt starter cultures (Col. 8, Example IV)

12. R1 is silent regarding the dissolved oxygen concentration and how it can be monitored by using an inert gas such as nitrogen.

13. R2 teaches using nitrogen to reduce the dissolved oxygen in milk. R2 teaches that in milk; the dissolved oxygen is about 10 ppm and in order to reduce it to about 2 ppm; one needs to add 40-50%, by volume, of nitrogen gas to the amount of milk (page 4, p 0023). R2 discloses that reducing the dissolved oxygen in milk will reduce smell and improve taste and smoothness (Abstract and Fig. 4). However, given that dissolved oxygen concentration is reduced upon using nitrogen, the gasified medium will be intrinsically more suitable for the growth anaerobic culture such as yogurt lactic starter cultures.

14. Regarding claims 8-9, given that R1 in combination with R2 disclose method as presently claimed, it is clear that such method would intrinsically result

in fermented milk with excellent smoothness and taste as presently claimed as well as hardness as presently claimed.

15. Regarding claims 10-12; it is clear that the method as disclosed by R1 and R2, would intrinsically result in fermented milk with penetration angle and hardness as presently claimed.

16. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R1 and adopt the teachings of R2 in using nitrogen to reduce the dissolved oxygen in the milk medium to accelerate the growth of the starter culture and hence reduce the incubation time as presently claimed. One would do so to benefit from processes which may be carried out on a continuous basis and having a shorter fermentation time, and to improve the overall economics of the process while using a gas such as nitrogen which does not affect organoleptic properties of the product. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in making a fermented product using nitrogen.

**2. Claims 5-6, and 8-12, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castberg et al. (US 5,453,256; hereinafter R1) in view of WO-0224870 (Examiner's Translation, hereinafter R3).**

17. R1 discloses a method of converting pasteurized milk into fermented milk in which the pasteurized milk is high temperature heat treated and carbonated with carbon dioxide and inoculated with starter culture followed by fermentation of the inoculated milk. (Abstract).

18. R1 discloses that while the conventional yoghurt process employs 43C as the incubation temperature; an incubation temperature of 30C may be employed (Col. 3, lines 14-17).

19. R1 discloses the advantage of the invention as shortening the fermentation time necessary and can thus lead to economics of the fermented milk and is particularly applicable to yoghurt production (Col. 4, lines 29-34). Therefore, the fermentation period is shorter than a fermentation period without using the inert gas as presently claimed.

**20. R1 discloses that the stimulation of lactic bacterial growth is, in part, due to removal of oxygen from the milk and thus lowering the redox potential. (col. 4, lines 40-43). R1 further adds that high oxygen content (e. g. in milk) retards the growth of yoghurt bacteria. (col. 4, lines 48-50)**

**21. R1 discloses that the high temperature heat treatment of milk can be at 80-85C for 20-30 minutes or at 90-95C for 3minutes. (col. 3, lines 10-15)**

**22. R1 discloses a method of converting milk into fermented milk comprising supplying heat treated milk, introducing the carbon dioxide into the heat treated milk and introducing the starter culture into the milk to instigate fermentation of milk. (col. 3, line 67 to col. 4 line 6, Examples 1 and 4).**

**23. Given the order of steps of sterilization, gasification, and fermentation of the yogurt substrate, as disclosed by R1, steps of claim 15 would be obvious to an artisan.**

24. R1 teaches using 1200 ppm of carbon dioxide which stimulates the starter culture and as a result the incubation time is reduced by 20% (Col. 5, lines 5-10). Given the effect of lowering the oxygen content of the medium (col. 4, lines 40-43) on the starter culture in reducing the incubation time, the finding, by the applicant, that the "increase of the lactic acid activity could be promoted without using any additives such as fermentation promoting substances by using inert gas to reduce the dissolved oxygen concentration" (Page 5 of the instant application, lines 10-21) was known in the art at the time the invention was made.

25. R1 gives an incubation temperature of 37C while using yoghurt starter cultures (Col. 8, Example IV)

26. R1 is silent regarding the dissolved oxygen concentration and how it can be monitored by using an inert gas such as nitrogen.

27. R3 discloses the process for the preparation of fermented milk. R3 discloses that one utilizes, advantageously, a gas which does not interfere in respiration or oxidation of microorganisms. This gas is chemically and biologically inert. The gas is preferably argon and particularly nitrogen or carbon dioxide. (Page 9, lines 25-30). R3 discloses that the gas pressure is 1-5 bar, and that the medium is gasified for 0.5 to 60 minutes.

28. Given that the medium is gasified for the duration disclosed by R3, it is clear that the dissolved oxygen concentration will be decreased to the levels as presently claimed.

29. Regarding claims 8-9, given that R1 in combination with R3 disclose method as presently claimed, it is clear that such method would intrinsically result in fermented milk with excellent smoothness and taste as presently claimed as well as hardness as presently claimed.

30. Regarding claims 10-12; it is clear that the method as disclosed by R1 and R3 would intrinsically result in fermented milk with penetration angle and hardness as presently claimed.

31. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R1 and adopt the teachings of R3 in using nitrogen to reduce the dissolved oxygen in the milk medium to accelerate the growth of the starter culture and hence reduce the incubation time as presently claimed. One would do so to benefit from processes which may be carried out on a continuous basis and having a shorter fermentation time, and to improve the overall economics of the process while using a gas such as nitrogen which does not affect organoleptic properties of the product. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in making a fermented product using nitrogen.

***Response to Arguments***

***Regarding The Declaration***

1. Mr. Hiroshi Horiuchi has executed a declaration in which yogurt is fermented under the influence of an inert gas such as nitrogen. The organoleptic

properties of the fermented product are described. These properties are described in quantitative terms as presently claimed.

2. Applicants argue that one skilled in the art would not have been motivated to combine R1 with R2 because in R1 carbon dioxide is used to displace oxygen in pasteurized milk while in R2 the reduction of dissolved oxygen concentration is carried out on raw milk for the purpose of improving the flavor of raw milk and since the purpose and timing of using carbon dioxide in R1 and those of the reduction of dissolved oxygen concentration in R2 are different, there is no motivation.

a. The primary reference (R1) is clearly disclosing the method of creating anaerobic conditions for the fermentation of milk together with the advantages of doing so. Please see col. 4, lines 40-43 and 48-50. Advantages such as reducing the fermentation time and firmness of the gel are also being presently claimed. However, attributes such as for instance taste of the product caused by carbonation which is known to people of skill in the art triggers looking for an inert gas to displace oxygen in the fermentation medium. R2 clearly teaches that nitrogen can be used to displace oxygen in the medium. Displacement of oxygen in raw milk or pasteurized milk are not different. The technique is known as “gas sparging” and is a routine technique in anaerobic bacteriology. There may be less dissolved oxygen in pasteurized milk due to the heat treatment which in fact will help the oxygen displacement by using a gas such as nitrogen.

It should also be realized that "obviousness under 103 is not negated because the motivation to arrive at the claimed invention as disclosed by the prior art does not agree with appellant's motivation", *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1990), *In re Tomlinson*, 150 USPQ 623 (CCPA 1966). If nitrogen is used for a different purpose in raw milk, it does not mean that it cannot be used for other purposes including the presently claimed use of nitrogen to create anaerobic conditions in a medium which is converted to yogurt upon fermentation.

2. Applicants argue that in the present invention, the reduction of dissolved oxygen concentration, by substituting with an inert gas such as nitrogen, is conducted for the purpose of improving physical properties (texture).

a. It should be realized that any improvement in the product will be due to a better growth of the yogurt culture due to more pronounced anaerobic conditions brought about by the removal of oxygen by gases such as nitrogen or carbon dioxide.

3. Applicants argue that R1 and R3 do not anticipate or render obvious the present invention in view of amended claim 5.

a. The only limitation which is not directly addressed by R1 or R3 is "5 ppm or less". However, R3 in addition to clearly using nitrogen for making yogurt, discloses that the nitrogen reservoir has a pressure of 1-5 bar, and the medium is gassed for 0.5 to 60 minutes. Those skilled in the art know that nitrogen at pressure and duration as disclosed by R3, necessarily reduces the dissolved oxygen in the milk medium to less than 5 ppm. Furthermore, it is noted that the solubility of oxygen in aqueous media is about 8 ppm at standard pressure and

temperature. Therefore, it does not take that long to remove the dissolved oxygen to levels below 5 ppm using a gas such as nitrogen or carbon dioxide. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

4. Applicants argue that there is simply no teaching or suggestion in R2 about reducing the dissolved oxygen after the sterilization of milk as recited in instant claim 15.

a. R1 discloses the gasification process after sterilization of the milk medium. Please see Examples 1 and 4, as well as top of col. 4, and claim 3 in R1. Therefore, R2 does not need to teach or suggest the sequence of steps. However, note that while R2 does not disclose all the features of the present claimed invention, R2 is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention.

***Conclusion***

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. JP 1—099019-A. This reference discloses the use of nitrogen or argon in removing the dissolved oxygen in the production of yogurt.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1794